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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,222	12/19/2001	Jerry Pelletier	073406-0701	4998
23373	7590	08/08/2006	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/025,222

Applicant(s)

PELLETIER ET AL.

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 66,72,88,91,105,106 and 109-120 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 66,88,91,105,106 and 109-120 is/are allowed.
- 6) ☒ Claim(s) 72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Application***

- [1] Claims 66, 72, 88, 91, 105-106, and 109-120 are pending in the application.
- [2] Applicant's amendment to the claims, filed on 6/20/2006, is acknowledged. This listing replaces all prior versions and listings of the claims.
- [3] A Declaration filed under 37 CFR 1.132 by Dr. Greg Moeck on 6/20/2006 is acknowledged.
- [4] A request to change inventorship, filed on 6/20/2006, is acknowledged.
- [5] Applicant's arguments filed on 6/20/2006 in response to the Office action mailed on 3/24/2006 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [6] The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

### ***Request to Correct Inventorship***

- [7] In view of the papers filed on 6/20/2006 and 12/8/2003, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding inventor Dominique Bergeron.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

***Claim Rejections - 35 USC § 102***

**[8]** The rejection of claim 72 under 35 U.S.C. 102(b) as being anticipated by O'Donnell et al. (WO 99/37661; cited in the IDS filed July 07, 2003 as reference A7) is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicant argues the skilled artisan would not conclude that the polypeptide of O'Donnell binds to the polypeptide of SEQ ID NO:4. According to applicant, polypeptides are known in the prior art that self-regulate and thus the carboxy-terminus of the polypeptide of O'Donnell may be blocked from binding to the polypeptide of SEQ ID NO:4. Applicant relies on the Declaration by Dr. Moeck (hereafter "Moeck Declaration") in support of this position. In summary, the Moeck Declaration cites two examples of polypeptides with domains that structurally interact to regulate the polypeptides' activity and states that the O'Donnell polypeptide could contain such interacting domains, whereby the C-terminus is blocked from binding to other polypeptides.

Applicant's argument is not found persuasive. There appears to be no dispute that the polypeptide of O'Donnell is 94% identical to the polypeptide of SEQ ID NO:2 herein, the C-terminus of the polypeptide of O'Donnell is identical to SEQ ID NO:6, and the polypeptide of O'Donnell and SEQ ID NO:2 herein are isolated from the same

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source, *i.e.*, *S. aureus*. Because the polypeptide of O'Donnell and SEQ ID NO:2 are nearly identical, are isolated from the same source, and because SEQ ID NO:2 binds SEQ ID NO:4 and thus does not appear to have a blocked C-terminus, one of ordinary skill in the art would also recognize, based on the preponderance of evidence, that it is more likely than not that the polypeptide of O'Donnell has SEQ ID NO:4-binding activity. Neither the reference of O'Donnell nor applicant has presented evidence or a line of reasoning to support the position that the *polypeptide of O'Donnell* has a blocked C-terminus that would prevent binding to SEQ ID NO:4. While the Declaration of Dr. Moeck refers to two prior art examples of such proteins, the polypeptides cited by Dr. Moeck in the Declaration are eukaryotic proteins and do not appear to have any relation or relevance to the bacterial protein of O'Donnell. Furthermore, in previous responses, applicant has taken the contradictory position that any protein with SEQ ID NO:6 at the C-terminus will bind to SEQ ID NO:4. For example, in the response filed on 9/1/2004 at p. 16, applicant asserts "it is reasonable to assume that ANY polypeptide....comprising the minimal domain of SEQ ID NO:6 would also possess the claimed activity of binding the polypeptide of SEQ ID NO:4" (emphasis in original). Because the polypeptide of O'Donnell and SEQ ID NO:2 are nearly identical, are isolated from the same source, because SEQ ID NO:2 binds SEQ ID NO:4 and thus does not appear to have a blocked C-terminus, in view of the absence of factual evidence to support applicant's allegation that the polypeptide of O'Donnell does not bind to SEQ ID NO:4, and applicant's previous statements of record that any polypeptide with SEQ ID NO:6 at the C-terminus will bind to SEQ ID NO:4, one of ordinary skill in the art would recognize that the

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polypeptide of O'Donnell has SEQ ID NO:4-binding activity. In this case, the examiner has provided a basis in fact and technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

If applicant continues to traverse the instant rejection on the ground that the polypeptide of O'Donnell does not have SEQ ID NO:4-binding activity, applicant is advised that this may necessitate a scope of enablement rejection based on applicant's admission and current position that not all polypeptides have the ability to bind SEQ ID NO:4.

### ***Conclusion***

**[9] Status of the claims:**

Claims 66, 72, 88, 91, 105-106, and 109-120 are pending.

Claims 66, 88, 91, 105-106, and 109-120 appear to be in a condition for allowance.

Claim 72 is rejected.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
David J. Steadman, Ph.D.  
Primary Examiner  
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